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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,950	11/18/2003	Miyuki Fukasawa	080542-0163	9191

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EXAMINER	
TRAN, SUSAN T	
ART UNIT	PAPER NUMBER
1615	
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07/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/714,950	FUKASAWA ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It appears that applicant's specification does not provide support for the limitation "sequential steps" as recited in line 2 of claim 9. The present specification, however, discloses the use of any commonly performed method to suspend the core material is acceptable (page 11, lines 23-25).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grisoni WO 02/24319 (US equivalent 7,067,153), in view of Iwasaki et al. US 4,349,454 or Zgoulli et al. US 5,456,985.

Grisoni teaches a microcapsule composition comprising hydrophilic polymer including HPMCP, and an oil component (column 3, lines 50-51 and 60-62). Grisoni further discloses the claimed process (abstract; and column 2, lines 50 through column 3, lines 1-36). The microcapsule is suitable for the encapsulation of cosmetic oils, vitamins, and the like (column 4, lines 52-59).

Grisoni does not explicitly teach gum arabic in the capsule composition.

Iwasaki teaches the use of gum arabic as a hydrophilic protective colloidal material in a microcapsule shell composition (abstract; and column 6, lines 35-52). Zgoulli teaches microcapsules comprising mixture of one or more gastro-resistant polymers with one or more non-gastro-resistant polymers (column 5, lines 1-5; and example 1). Gastro-resistant polymer includes hydroxypropylmethyl cellulose phathlate (HPMCP) (column 3, lines 36-38). Non-gastro-resistant polymer includes gum arabic (column 4, lines 60-62). The microcapsule is useful for the encapsulation of a wide range of oils including food oils, and pharmaceutical oils such as peanut oil, fish oil, vitamins, and the like (column 5, lines 15-53). Thus, it would have been obvious to one of ordinary skill in the art to modify the microcapsule composition of Grisoni using gum arabic as an oil component in view of the teachings of Iwasaki or Zgoulli, because Iwasaki and Zgoulli teach the use of gum arabic in capsule shell composition to obtain an improve stability composition, and because Grison teaches the incorporation of an oil component (emulsifier) in a capsule shell composition.

Claims 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zgoulli et al. US 5,456,985, in view of Matsukawa et al. US 3,660,304.

Zgoulli teaches a process to obtain microcapsules comprising mixing one or more gastro-resistant polymers with one or more non-gastro-resistant polymers to form a first mixture, mixing an oily liquid to be encapsulated with a non-ionic surfactant to form a second mixture, and mixing said first and second mixtures to form the microcapsules (column 5, lines 1-5; and example 1). Gastro-resistant polymer includes hydroxypropylmethyl cellulose phathlate (HPMCP) (column 3, lines 36-38). Non-gastro-resistant polymer includes gum arabic (column 4, lines 60-62). The microcapsule is useful for the encapsulation of a wide range of oils including food oils, and pharmaceutical oils such as peanut oil, fish oil, vitamins, and the like (column 5, lines 15-53).

It is noted that Zgoulli teaches different order of adding the ingredients, however, in the absence of unexpected result, selection of any order of mixing ingredients is prima facie obvious. *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930). Thus, it would have been obvious to one of ordinary skill in the art to, by routine experimentation optimize the process of Zgoulli to select the order of adding the ingredients that fall within the claimed invention. This is because Zgoulli teaches using a similar process steps to obtain the microcapsules having the properties desired by the applicant, *i.e.*, coating layer consists of an enteric polymer and gum arabic, low toxic residues, and prolonged storage (column 3, lines 15-25; column 5, lines 61-62; and column 6, lines 5-13).

It is noted that Zgoulli does not explicitly teach the boiling point of the oily liquid core. However, such limitation is inherent because it is well known in the art that most oils have boiling point of 100°C or higher. See for example, fish oil has boiling point of at least 150°C (Matsukawa et al. US 3,660,304).

Response to Arguments

Applicant's arguments filed 04/27/07 have been fully considered but they are not persuasive.

Applicant argues that Zgoulli teaches adding an oil into a mixture of a gastro-resistant polymer such as CAP and gum arabic to form a microcapsule (column 6. lines 58-62). Accordingly, Zgoulli has a different order of addition from the present invention leading to a product with different physical characteristics from compositions derived using the current method.

However, the examiner disagrees with the indication that different order of addition leading to a product with different physical characteristics, for the following reasons: 1) applicant has not shown any unexpected result over the product of Zgoulli; 2) Zgoulli teaches microcapsules having properties desired by the applicant, *i.e.*, coating layer consists of an enteric polymer and gum arabic, low toxic residues, and prolonged storage (column 3, lines 15-25; column 5, lines 61-62; and column 6, lines 5-13); and 3) applicant's disclosure supports the fact that selection of any order of adding ingredients is obvious (see specification at page 9, lines 20-22: *even if this order (adding ingredients) is reversed a sufficiently strong stabilized microcapsule can be*

prepared). Accordingly, the present claims are obvious over Zgoulli, because selection of any order of mixing ingredients is prima facie obvious. *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930); and see also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946), selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results.

Applicant argues that Iwasaki teaches the use of a hydrophobic organic solvent Thus, Iwasaki never teaches the present invention and directs a person skilled in the art to conditions outside the current invention. Based on the above, the claims of the current invention are not obvious over the teachings Grisoni, and Iwasaki.

In response to applicant's arguments, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the present case, Iwasaki is relied upon solely for the teaching of using gum arabic in a microcapsule shell is well known in pharmaceutical art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SUSAN TRAN
PRIMARY EXAMINER

S. Tran
Art Unit 1615